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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,993	02/17/2004	James D. Lewis JR.	HT-5755 DIV (1417YP1044)	1329
7590 01/21/2005			EXAMINER	
Matthew J. Gryzlo, Esq. Wallenstein Wagner & Rockey, Ltd. 311 S. Wacker Drive, 53rd Floor Chicago, IL 60606-6630			MOHANDESI, JILA M	
			ART UNIT	PAPER NUMBER
			3728	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/779,993

**Applicant(s)**

LEWIS ET AL.

**Examiner**

Jila M Mohandesi

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/17/04</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-13 in the reply filed on November 08, 2004 is acknowledged. The traversal is on the ground(s) that the search and examination of claims readable on the separate groups of claims would not impose a serious burden on the Examiner. This is not found persuasive because the search for the group of claims 1-13 is not the same and is in a different area than the search for the group of claims 14-21.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 08, 2004.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. publication No. Lewis, JR. et al. (2002/0124526) herein after Lewis. Lewis discloses a container for holding albumin comprising: a flexible polymeric film formed into a bag (12) having a cavity enclosed by a first wall, an opposing second wall, and seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container, wherein a concentration of albumin is stored within the fluid-tight chamber. See Figure s 3 and 4 embodiments.

With respect to claim 2, see paragraph 47.

With respect to the fold area note fold area 67 in Figure 4 embodiment.

With respect to claims 11 and 12, see Figure 9 embodiment and paragraph 48.

With respect to claims 9 and 10 see claims 47 and 48 of Lewis.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. (4,692,361) in view of Sano et al. (6,326,010). Johnson '361

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discloses a container for holding products to be maintained and removed under sterile conditions, comprising: a flexible polymeric film formed into a bag having a cavity enclosed by a first wall, an opposing second wall, and seals about a periphery of the first and second walls, the seals joining an interior portion of the opposing first and second walls and creating a fluid-tight chamber within the cavity of the container. See Figures 1 and 2 embodiments and column 1, lines 11-21. Johnson '361 discloses that the flexible containers are utilized in medical industry for containing, inter alia, parenteral solutions, dialysis solutions, frozen drugs and plasma. Sano '010 discloses that Albumin, particularly human serum albumin, is a protein mostly included in blood plasma. Sono '010 also discloses that it is desirable to store albumin a sterilized plastic vessel. Based on the teaching of Sono'010 that albumin is included in plasma and Johnston '361 discloses storing plasma in the flexible bags, it would have been obvious to one of ordinary skill in the art at the time the invention was made to also store albumin in the flexible bags of Johnson '361.

With respect to claims 5 and 8, see column 6, lines 57-61.

With respect to claims 11 and 12, see Figure 1 embodiment and column 3, lines 37-49.

With respect to claim 2 official notice is taken that it is old and conventional to mix albumin with sterilized water and stabilizers.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claims 1 and 3 above, and further in view of Bacehowski et al. (4,910,147). Johnston '361 as modified above discloses all the limitations of the claims

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except for the flexible bag further comprising an aperture adjacent an edge opposing the fitment. Bacehowski '147 discloses a flexible bag with an aperture adjacent an edge opposing the fitment to facilitate hanging of the flexible bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an aperture adjacent an edge opposing the fitment of the flexible bag of Johnston '361 as taught by Bacehowski '147 to facilitate hanging of the flexible bag.

9. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the above references as applied to claims 1, 3 and 5 above, and further in view of Bell et al. (4,936,456). Johnston '361 as modified above discloses all the limitations of the claims except for it are silent about the type of seal being used. Bell '456 discloses that chevron seals can be used instead of linear seals for closing the edges of a flexible bag. As a result of the chevron seal construction, relatively log tabs are formed to facilitate opening through stripping of the gussets from the bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide chevron seals in the flexible bag of Johnston '361 as taught by Bell '456 to facilitate opening through stripping of the gussets from the bag.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shown are flexible bags analogous to applicant's instant invention.

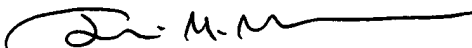
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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M Mohandesi whose telephone number is (571) 272-4558. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**JILA M. MOHANDESI  
PRIMARY EXAMINER**

  
Jila M Mohandesi  
Primary Examiner  
Art Unit 3728

JMM  
January 18, 2005